UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: September 25, 2020

Subject: Efficacy Review for Peroxide Multi Surface Cleaner and Disinfectant, EPA Reg. No. 1677-238
Electrostatic spray- DP Barcodes: 458214, 458982 E-Submission: 51088
SARS-CoV-2- DP Barcode: 459194 E-submission: 54351

From: Kristen Willis, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Jacquie Hardy, Team 34 / Cody Kendrick
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Ecolab, Inc.
370 Wabasha Street North
St. Paul, MN 55102

Formulation from the Label:

Active Ingredient(s)	% by wt.
Hydrogen peroxide	8.0%
Other Ingredients	92.0%
Total	100.0%

I BACKGROUND

Product Description (as packaged, as applied): Liquid concentrate

Submission type: Label amendment (A570)

Currently registered efficacy claim(s): disinfectant (bactericidal, virucidal and fungicidal), non-food contact sanitizer for hard nonporous and soft surfaces.

Requested action(s): Add directions for use for electrostatic spray and claims for SARS-CoV-2.

Documents considered in this review:
Electrostatic spray- E-submission 51088

- Letter from applicant to EPA dated June 2, 2020 and July 27, 2020
- Data Matrix (EPA Form 8570-35) dated July 27, 2020
- 6 efficacy studies (MRID 51172201-6)
- Proposed label dated 08/27/2020
- Email from EPA (K. Willis) to Ecolab (E. Black) dated May 29, 2020 confirming that the outlined approach for electrostatic spray (ESS) was acceptable. Note: The submission predated EPA's guidance for adding directions for use for electrostatic spray.
- Certificates of analysis dated 9/20/2019
- Wetness testing results for electrostatic spray (presentation dated June 2, 2020)
- Rationale to support altering the default directions and PPE in the guidance dated August 7, 2020. Note: This document was sent to RASSB for review and the findings included here for convenience.

SARS-CoV-2- E-submission 54351

- Letter from applicant to EPA dated August 27, 2020
- Email from EPA (K. Willis) to Ecolab (E. Black) dated August 21, 2020.
- Data Matrix (EPA Form 8570-35) dated August 27, 2020
- Confidential Statement of Formula (EPA Form 8670-4) dated August 11, 2017
- 1 efficacy study (MRID 51252001)
- Proposed label dated 08/27/2020

II PROPOSED DIRECTIONS FOR USE

"For use as a Virucide*: Dilute (according to use directions) OR (at 1:32 (4 fl. oz./gal)) OR (at 1:21.3 (6 fl. oz./gal)). Pre-clean heavily soiled areas. Apply Use Solution by coarse trigger sprayer to hard, non-porous environmental surfaces. Spray 6-8 inches from the surface; making sure to wet surfaces thoroughly. All surfaces must remain wet for the required time indicated in the directions for use. Wipe surfaces (or allow to air dry).
VIRUCIDAL* (kills) at 1:32 dilution (4 fl. oz./gal) against the following viruses modified in the presence of 5% blood serum.
In 30 seconds diluted in 400 ppm hard water:
*SARS Coronavirus 2 (SARS-CoV-2) (BEI Resources NR-52281) (Strain Isolate USA-WA 1/2020).

General Directions for use with Electrostatic Spraying
Remove by-standers from the area to be treated. Do not use for treatment of humans, air, or for fumigation. Plan the spray routine to minimize unnecessary exposure to treated areas (for example, begin applying product in the back of the room/area and work towards the front of the room/area). Once treatment is completed, allow for a 15 minute resettling time before reentry to the treated space. Consider material compatibility and potential for damage prior to application.

For use as a (Multi-Surface) One-Step Cleaner and Disinfectant by Electrostatic Spraying
To disinfect hard, non-porous surfaces, dilute (according to use directions) OR (at 1:21.3 (6 fl. oz./gal)) OR (at 1:32 (4 fl. oz./gal)). For visibly soiled areas, pre-cleaning is required. Apply use solution with electrostatic sprayer to hard, non-porous environmental surfaces. Spray approximately 6 to 12 inches from the surfaces; making sure to wet surfaces thoroughly. All surfaces must remain wet for the required contact time indicated in the directions for use,

reapplying if necessary. Let air dry. When using on food contact surfaces, thoroughly rinse all treated surfaces with potable water.
For use as a Virucide* with Electrostatic Spraying: Dilute (according to use directions) OR (at 1:21.3 (6 fl. oz./gal)) OR (at 1:32 (4 fl. oz./gal)). For visibly soiled areas, pre-cleaning is required. Apply use solution with electrostatic sprayer to hard, non-porous environmental surfaces. Spray approximately 6 to 12 inches from the surfaces; making sure to wet surfaces thoroughly. All surfaces must remain wet for the required time indicated in the directions for use, reapplying if necessary. Let air dry. When using on food contact surfaces, thoroughly rinse all treated surfaces with potable water."

III AGENCY STANDARDS

EPA expedited review for adding electrostatic spray application directions: https://www.epa.gov/pesticide-registration/expedited-review-adding-electrostatic-spray-application-directions-use

Per 2018 810.2200 guideline, testing for viruses should be conducted using ASTM E1053. In a deviation from the guideline, EPA requested 3 product lots at the LCL be tested for SARS-CoV-2.

IV STUDY SUMMARIES

1.	**MRID**	51252001		
Study Objective		Disinfection – virucidal		
Testing Lab; Lab Study ID		ALG; A30366		
Experimental Start Date		08/05/2020	**Study Completion Date:**	08/27/2020
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		SARS-Related Coronavirus 2, BEI Resources NR-52281, Strain Isolate USA-WA1/2020		
Indicator Cell Culture		Vero E6 cells (ATCC CRL-1586)		
Test Method		ASTM E1053-11		
Application Method		Each dried virus film was individually exposed to a 2.00 ml aliquot of the use dilution of the test substance and held for the duration of the contact time.		
Test Substance Preparation	**Name/ID**	Peroxide Multi Surface Cleaner and Disinfectant		
	Lots ☐ **1** ☐ **2** ☒ **3**	5130JEG900, 4389MW5100, 4110MWA900		
	Preparation	Tested concentration: LCL 2293 ppm Tested Dilution: 4 oz/gallon defined as 2.83 g test substance + 97.17 g 400 ppm AOAC synthetic hard water (Batch 5130JEG900) and as 2.90 g test substance + 97.10 g 400 ppm AOAC synthetic hard water (Batches 4389MW5100 and 4110MWA900)		
Soil load		5% fetal bovine serum in viral inoculum		
Carrier type, # per lot		Glass carriers, 1 carrier/lot		
Test conditions		Contact time: 30 seconds Temperature: 19.2°C Relative humidity: 55.53%		
Neutralizer		Sephadex LH-20 gel column		
Reviewer comments		The following amendments were made the protocol:		

(i.e. protocol deviations and amendments, retesting, control failures, etc.)	– To correct a typographical error on page 8, reference #8 should be "Health Canada, April, 2020. Guidance Document - Safety and Efficacy Requirements for Surface Disinfectant Drugs." – To correct a typographical error on page 10, the "Yes" box should be marked instead of the "No" box under Protocol Attachments. Unforseen circumstances: The initial assay performed on August 5, 2020 was repeated on August 14, 2020 in order to obtain valid results. There was no viral growth in the input virus control or any of the neutralization controls, even though there was growth in the dried virus control. Because there was no growth observed, there was the question of whether the input virus control had been performed, prior to inoculation of the indicator cell cultures. The low titer virus that is used in the neutralization control also often comes from the serial dilutions of the input virus control, which further indicates that it hadn't been performed. Because of the observed result from the neutralization controls, the results obtained from the August 5, 2020 assay are considered invalid. See Attachment I for the invalid data from the August 5, 2020 assay.

2.	**MRID**	51172201		
Study Objective		Disinfectant (bactericidal) efficacy test when applied by an electrostatic sprayer		
Testing Lab; Lab Study ID		Ecolab Schuman Campus		
Experimental Start Date		05/04/2020	**Study Completion Date:**	06/10/2020
Test organism(s) **☐ 1 ☒ 2 ☐ 3 ☐ 4+**		Pseudomonas aeruginosa ATCC #15442 and Staphylococcus aureus ATCC #6538		
Test Method		Modified AOAC Germicidal Spray Test 961.02(Microbiology Services Standard Operating Procedure MS010)		
Application Method		Electrostatic spray; The electrostatic sprayer was sprayed onto the glass carriers from a distance of 12 inches for 2 seconds.		
Test Substance Preparation	**Name/ID**	Peroxide Multi Surface Cleaner and Disinfectant (formula code 919267)		
	Lots **☒ 1 ☐ 2 ☐ 3**	Lot # 1389JE4900		
	Preparation	Tested concentration: greater than Nominal, production lot Tested Dilution: 6 oz/gallon (97.2 g of product into 1999.8 g of 200 ppm AOAC hard water)		
Soil load		5% fetal bovine serum in viral inoculum		
Carrier type, # per lot		Glass slides, 60 per organism		
Test conditions		Contact time: 3 minutes Temperature: 15-30°C Relative humidity: N/A		
Neutralizer		Letheen broth + 0.5% Sodium Thiosulfate		

Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	The study was not conducted under GLP. The electrostatic sprayer used in the testing was the Victory Cordless Electrostatic Handheld Sprayer. The study also included the weights for 5 different sprays using the electrostatic sprayer: Average = 1.29 grams

3.	MRID	51172202		
Study Objective		Disinfectant (virucidal) efficacy test when applied by an electrostatic sprayer		
Testing Lab; Lab Study ID		Ecolab Schuman Campus		
Experimental Start Date		05/01/2020	**Study Completion Date:**	06/10/2020
Test organism(s) **☐ 1 ☒ 2 ☐ 3 ☐ 4+**		Feline calicivirus ATCC VR-782		
Test Method		Microbiology Services Standard Operating Procedure MS505-3.0		
Application Method		Electrostatic spray; The electrostatic sprayer was sprayed onto the glass carriers from a distance of 12 inches for 2 seconds.		
Test Substance Preparation	**Name/ID**	Peroxide Multi Surface Cleaner and Disinfectant (formula code 919267)		
	Lots **☒ 1 ☐ 2 ☐ 3**	Lot # 1389JE4900		
	Preparation	Tested concentration: greater than Nominal, production lot Tested Dilution: 6 oz/gallon (97.2 g of product into 1999.8 g of 200 ppm AOAC hard water)		
Indicator Cell Culture		CRFK Cells A TCC CCL-94		
Soil load		5% fetal bovine serum in viral inoculum		
Carrier type, # per lot		100 x 15 mm glass petri dish, 2		
Test conditions		Contact time: 45 seconds Temperature: 15-30°C Relative humidity: N/A		
Neutralizer		Sephadex column		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		The study was not conducted under GLP. The electrostatic sprayer used in the testing was the Victory Cordless Electrostatic Handheld Sprayer.		

4.	**MRID**	51172203
Study Objective		Disinfectant (bactericidal) efficacy test when applied by an electrostatic sprayer
Testing Lab; Lab Study ID		Ecolab Schuman Campus

Experimental Start Date		06/09/2020	**Study Completion Date:**	07/01/2020
Test organism(s) **☐ 1 ☒ 2 ☐ 3 ☐ 4+**		Pseudomonas aeruginosa ATCC #15442 and Staphylococcus aureus ATCC #6538		
Test Method		Modified AOAC Germicidal Spray Test 961.02(Microbiology Services Standard Operating Procedure MS010)		
Application Method		Electrostatic spray; The electrostatic sprayer was sprayed onto the glass carriers from a distance of 12 inches for 2 seconds.		
Test Substance Preparation	**Name/ID**	Peroxide Multi Surface Cleaner and Disinfectant (formula code 919267)		
	Lots **☐ 1 ☒ 2 ☐ 3**	Lot # 5130JEG900, Lot # 4389MW5100		
	Preparation	Tested concentration: LCL 2290 ppm Tested Dilution: 4 oz/gallon defined as 28.73 g test substance + 971.27 g 400 ppm AOAC synthetic hard water (Batch 5130JEG900) and as 28.80 g test substance + 971.20 g 400 ppm AOAC synthetic hard water (Batches 4389MW5100)		
Soil load		5% fetal bovine serum in viral inoculum		
Carrier type, # per lot		Glass slides, 18 x 36 mm, 10 per organism per batch		
Test conditions		Contact time: 5 minutes Temperature: 15-30°C Relative humidity: N/A		
Neutralizer		Letheen broth + 0.5% Sodium Thiosulfate		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		The study was not conducted under GLP. The electrostatic sprayer used in the testing was the Victory Cordless Electrostatic Handheld Sprayer. The study also included the weights for 5 different sprays per batch on 2 different days using the electrostatic sprayer: Averages across batches and days were 1.28 grams, 0.87 grams, 1.11 grams and 1.10 grams		

5.	**MRID**	51172204		
Study Objective		Disinfectant (bactericidal) efficacy test when applied by an electrostatic sprayer		
Testing Lab; Lab Study ID		Ecolab Schuman Campus		
Experimental Start Date		06/09/2020	**Study Completion Date:**	07/01/2020
Test organism(s) **☐ 1 ☒ 2 ☐ 3 ☐ 4+**		Pseudomonas aeruginosa ATCC #15442 and Staphylococcus aureus ATCC #6538		
Test Method		Modified AOAC Germicidal Spray Test 961.02(Microbiology Services Standard Operating Procedure MS010)		
Application Method		Electrostatic spray; The electrostatic sprayer was sprayed onto the glass carriers from a distance of 12 inches for 2 seconds.		
Test Substance Preparation	**Name/ID**	Peroxide Multi Surface Cleaner and Disinfectant (formula code 919267)		
	Lots **☐ 1 ☒ 2 ☐ 3**	Lot # 5130JEG900, Lot # 4389MW5100		

	Preparation	Tested concentration: LCL 3448 ppm Tested Dilution: 6 oz/gallon defined as 43.09 g test substance + 956.91 g 200 ppm AOAC synthetic hard water (Batch 5130JEG900) and as 43.20 g test substance + 956.80 g 200 ppm AOAC synthetic hard water (Batches 4389MW5100)
Soil load		5% fetal bovine serum in viral inoculum
Carrier type, # per lot		Glass slides, 18 x 36 mm, 10 per organism per batch
Test conditions		Contact time: 3 minutes Temperature: 15-30°C Relative humidity: N/A
Neutralizer		Letheen broth + 0.5% Sodium Thiosulfate
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		The study was not conducted under GLP. The electrostatic sprayer used in the testing was the Victory Cordless Electrostatic Handheld Sprayer. The study also included the weights for 5 different sprays per batch on 2 different days using the electrostatic sprayer: Averages across batches and days were 1.93 grams, 1.95 grams, 1.60 grams and 1.86 grams

6.	MRID	51172205		
Study Objective		Disinfectant (virucidal) efficacy test when applied by an electrostatic sprayer		
Testing Lab; Lab Study ID		Ecolab Schuman Campus		
Experimental Start Date		06/09/2020	**Study Completion Date:**	07/01/2020
Test organism(s) **☐ 1 ☒ 2 ☐ 3 ☐ 4+**		Feline calicivirus ATCC VR-782		
Test Method		Microbiology Services Standard Operating Procedure MS505-3.0		
Application Method		Electrostatic spray; The electrostatic sprayer was sprayed onto the glass carriers from a distance of 12 inches for 2 seconds.		
Test Substance Preparation	**Name/ID**	Peroxide Multi Surface Cleaner and Disinfectant (formula code 919267)		
	Lots **☒ 1 ☐ 2 ☐ 3**	Lot # 5130JEG900 and 4389MW5100		
	Preparation	Tested concentration: LCL, 2299 ppm Tested Dilution: 4 oz/gallon 28.72 g of product into 971.27 g of 400 ppm AOAC hard water (Lot # 5130JEG900) and 28.79 g of product into 971.20 g of 400 ppm AOAC hard water (Lot # 4389MW5100)		
Indicator Cell Culture		CRFK Cells A TCC CCL-94		
Soil load		5% fetal bovine serum in viral inoculum		
Carrier type, # per lot		100 x 15 mm glass petri dish, 1 per batch		
Test conditions		Contact time: 2 minutes Temperature: 15-30°C Relative humidity: N/A		

Neutralizer	Sephadex column
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	The study was not conducted under GLP. The electrostatic sprayer used in the testing was the Victory Cordless Electrostatic Handheld Sprayer.

7.	MRID	51172206		
Study Objective		Disinfectant (virucidal) efficacy test when applied by an electrostatic sprayer		
Testing Lab; Lab Study ID		Ecolab Schuman Campus		
Experimental Start Date		06/09/2020	**Study Completion Date:**	07/01/2020
Test organism(s) **☐ 1 ☒ 2 ☐ 3 ☐ 4+**		Feline calicivirus ATCC VR-782		
Test Method		Microbiology Services Standard Operating Procedure MS505-3.0		
Application Method		Electrostatic spray; The electrostatic sprayer was sprayed onto the glass carriers from a distance of 12 inches for 2 seconds.		
Test Substance Preparation	**Name/ID**	Peroxide Multi Surface Cleaner and Disinfectant (formula code 919267)		
	Lots **☒ 1 ☐ 2 ☐ 3**	Lot # 5130JEG900 and 4389MW5100		
	Preparation	Tested concentration: LCL, 3448 ppm Tested Dilution: 6 oz/gallon 43.11 g of product into 956.92 g of 200 ppm AOAC hard water (Lot # 5130JEG900) and 43.22 g of product into 956.79 g of 200 ppm AOAC hard water (Lot # 4389MW5100)		
Indicator Cell Culture		CRFK Cells A TCC CCL-94		
Soil load		5% fetal bovine serum in viral inoculum		
Carrier type, # per lot		100 x 15 mm glass petri dish, 1 per batch		
Test conditions		Contact time: 45 seconds Temperature: 15-30°C Relative humidity: N/A		
Neutralizer		Sephadex column		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		The study was not conducted under GLP. The electrostatic sprayer used in the testing was the Victory Cordless Electrostatic Handheld Sprayer.		

V STUDY RESULTS

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results			Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
			Lot			
			5130JEG900	4389MW5100	4110MWA900	
30 seconds, 4 oz/gallon in 400 ppm AOAC hard water, 5% fetal bovine soil						
51252001	SARS-Related Coronavirus 2, BEI Resources NR-52281, Strain Isolate USA-WA1/2020	10^{-1} to 10^{-6} dilution*	Complete inactivation	Complete inactivation	Complete inactivation	6.05
		Log_{10} $TCID_{50}$/carrier	≤ 0.80	≤ 0.80	≤ 0.80	
		Log Reduction	≥ 5.25	≥ 5.25	≥ 5.25	

*Dilution refers to the fold of dilution from the virus inoculum. Post neutralized sample was considered the 10^{-1} dilution.

Disinfection – Electrostatic Spray
Bactericidal Efficacy

MRID	Organism	Test conditions	Lot #	No. of carriers exhibiting growth/Total No. tested	Average Log_{10} CFU/carrier
51172201	Pseudomonas aeruginosa ATCC #15442	3 minutes, 6 oz/gallon, 5% FBS, 200 ppm hard water	1389JE4900	0/60	6.37
51172203		5 minutes, 4 oz/gallon, 5% FBS, 400 ppm hard water	5130JEG900	0/10	5.93
			4389MW5100	0/10	
51172204		3 minutes, 6 oz/gallon, 5% FBS, 200 ppm hard water	5130JEG900	0/10	5.79
			4389MW5100	0/10	

MRID	Organism	Test conditions	Lot #	No. of carriers exhibiting growth/Total No. tested	Average Log_{10} CFU/carrier
51172201	Staphylococcus aureus ATCC #6538	3 minutes, 6 oz/gallon, 5% FBS, 200 ppm hard water	1389JE4900	0/60	6.03
51172203		5 minutes, 4 oz/gallon, 5% FBS, 400 ppm hard water	5130JEG900	0/10	6.1
			4389MW5100	0/10	
51172204		3 minutes, 6 oz/gallon, 5% FBS, 200 ppm hard water	5130JEG900	0/10	6.14
			4389MW5100	0/10	

Disinfection – Electrostatic Spray
Virucidal Efficacy

MRID	Organism	Lot #	Test Conditions	Description	Results		Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
51172202	Feline calicivirus ATCC VR-782	1389JE4900	45 seconds, 6 oz/gallon, 5% FBS, 200 ppm hard water	Replicate	1	2	7.05
				10^{-1} to 10^{-5} dilution	Complete inactivation	Complete inactivation	
				Log_{10} $TCID_{50}$/carrier	≤ 0.80	≤ 0.80	
				Log Reduction	≥ 6.25	≥ 6.25	
51172205		5130JEG900	2 minutes, 4 oz/gallon, 5% FBS, 400 ppm hard water	10^{-1} to 10^{-5} dilution	Complete inactivation		6.05
				Log_{10} $TCID_{50}$/carrier	≤ 0.80		
				Log Reduction	≥ 5.25		

MRID	Organism	Lot #	Test Conditions	Description	Results	Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
		4389MW5100		10^{-1} to 10^{-5} dilution	Complete inactivation	
				Log_{10} $TCID_{50}$/carrier	≤ 0.80	
				Log Reduction	≥ 5.25	
51172206		5130JEG900	45 seconds, 6 oz/gallon, 5% FBS, 200 ppm hard water	10^{-1} to 10^{-5} dilution	Complete inactivation	6.55
				Log_{10} $TCID_{50}$/carrier	≤ 0.80	
				Log Reduction	≥ 5.75	
		4389MW5100		10^{-1} to 10^{-5} dilution	Complete inactivation	
				Log_{10} $TCID_{50}$/carrier	≤ 0.80	
				Log Reduction	≥ 5.75	

Wetness testing

In addition to the efficacy testing, the registrant also conducted wetness testing to demonstrate that the surface remains visibly wet over the duration of the contact time. Pictures were provided as well as weight measurements. Over the course of a 10-minute contact time, < 5% of the disinfectant applied via electrostatic spray evaporated. In addition it was clearly visible in photos.

MRID	Average weight (g) for 5 sprays of 2-seconds each
51172201	1.29
51172203	Averages across batches and days were 1.28 grams, 0.87 grams, 1.11 grams and 1.10 grams
51172204	Averages across batches and days were 1.93 grams, 1.95 grams, 1.60 grams and 1.86 grams

51172205	Averages across the two tested batches were 1.28 and 0.87
51172206	Averages across the two tested batches were 1.93 and 1.95

Rationale to supporting changing the default label language and PPE for electrostatic spray.
This document was reviewed by the AD Risk Assessment Science Support Branch and their finding are included here:

"In looking at the white paper and the corrected vapor pressure table provided via email (and applying some corrections to the application rates), at the lower concentration (2600 ppm), the vapor pressure ranges from $5.3E^{-4}$ to $8.5E^{-4}$ mmHg

The current electrostatic sprayer (ESS) information provided on EPA's website (https://www.epa.gov/pesticide-registration/expedited-review-adding-electrostatic-spray-application-directions-use) states that "(f)or high vapor pressure chemicals (greater than 1. X 10^{-4} mm Hg)…use half face respirators with chemical specific cartridges and N95 filters".

- Therefore, half face respirators with chemical specific cartridges and N95 filters should be added to the label.
- Additionally, add the following to the label (again, following the current ESS information):
    - Place the electrostatic spray function in the ON position for electrostatic spray models that have the functionality to toggle ON/OFF.
    - Specify that bystanders and pets must not be in the room during application"

VI STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
5125001	Disinfectant, virucidal	Hard nonporous	Liquid, 4 oz/gallon	30 seconds	5% FBS	400 ppm hard water	SARS-Related Coronavirus 2, BEI Resources NR-52281	**Yes**
51172201	Disinfectant, bactericidal	Hard nonporous	Electrostatic spray, 6 oz/gallon	3 minutes	5% FBS	200 ppm hard water		**No,** testing above nominal

51172203			Electrostatic spray, 4 oz/gallon	5 minutes		400 ppm hard water	• *Pseudomonas aeruginosa* ATCC #15442 • *Staphylococcus aureus* ATCC #6538	**Yes**
51172204			Electrostatic spray, 6 oz/gallon	3 minutes		200 ppm hard water		**Yes**
51172202	Disinfectant, virucidal	Hard nonporous	Electrostatic spray, 6 oz/gallon	45 seconds	5% FBS	200 ppm hard water	• Feline calicivirus ATCC VR-782	**No,** testing above nominal
51172205			Electrostatic spray, 4 oz/gallon	2 minutes		400 ppm hard water		**Yes**
51172205			Electrostatic spray, 6 oz/gallon	45 seconds		200 ppm hard water		**Yes**

VII LABEL COMMENTS

Label Date: 08/27/2020

1. The proposed label claims that the product, Peroxide Multi Surface Cleaner and Disinfectant, when diluted at 4 fl oz. per gallon of 400 ppm hard water, is an effective disinfectant against the following on hard nonporous surfaces in the presence of 5% organic soil for a 30-second contact time:

   SARS Coronavirus 2 (BEI NR-52281)

   These claims are **acceptable** as they are supported by the submitted data.

2. The proposed label claims that the product, Peroxide Multi Surface Cleaner and Disinfectant, when diluted at 4 fl oz. per gallon in 400 ppm hard water or 6 fl oz. per gallon, in 200 ppm hard water is an effective disinfectant and virucide on hard nonporous surfaces when applied via electrostatic spray according to the appropriate directions for use. This is based on testing against the folllowing:

   Peudomonas aeruginosa ATCC #15442
   Staphylococcus aureus ATCC #6538
   Feline calicivirus ATCC VR-782

   These claims are **acceptable** as they are not supported by the submitted data and support bridging to the other bacteria and viruses on the label.

3. Make the following changes to the proposed label:
   a. Throughout the label, all marketing claims for SARS-CoV-2 should specify effectiveness on hard, non-porous surfaces.
   b. Throughout the label, recommend that statements such as “Treated surfaces must remain wet“ and similar statements in the use directions be clarified to “Treated surfaces must remain visibly wet” for the contact time.
   c. On page 1 of the proposed label,
      - Remove “all-in-one” as this claim is false and misleading. An acceptable alternative is “multipurpose”.
   d. On page 6 of the proposed label,
      - half face respirators with chemical specific cartridges and N95 filters should be added to the label per the electrostatic spray guidance
      - Add the following: “Place the electrostatic spray function in the ON position for electrostatic spray models that have the functionality to toggle ON/OFF.”
      - Specify that bystanders and pets must not be in the room during application
      - Specify that the spray droplet particle size (regardless of the ability to change nozzles that impact particle size) should be limited to a volume median diameter (VMD) ≥40 µm1
   e. On page 13 of the proposed label,
      - Qualify “eliminates” in the claim “Kills (Eliminates) SARS-Related Coronavirus 2 (SARS-CoV-2) (USA-WA1/2020) (causative agent of COVID-19) (the virus that causes COVID-19)” with the log reduction achieved (e.g. 99.999%). Alternatively remove “eliminates” from the claim.

- Recommend “fighting” be removed or revised to “killing” as it may be misleading to the end user regarding the activity of the product.
- Qualify the claim “Disinfects as it cleans” with “when used according to disinfection instructions.”